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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,432	04/10/2001	Karen A. Ketchum	CL001013-CIP	8734

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 04/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/829,432

Applicant(s)

KETCHUM ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8,9 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,8,9 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 1/13/03 in Paper No: 7. Claims 4, 8, 9 and 24-29 are pending.
2. Applicants changing of the title is acknowledged. Thus, the objection is withdrawn.
3. Applicant has deleted all hyperlinks from the specification. Thus, the objection is withdrawn.
4. It is noted that the Applicant has provided corrected drawings in response to the previous Office Action. The draftsman has approved it.
5. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph, withdrawn.

7. Applicant's arguments are persuasive and have obviated the rejection under 35 USC 112, first paragraph for lacking enabling disclosure for claims 24 and 28.

Claim Rejections - 35 USC § 112, second paragraph, maintained

6. Claim 24 stands rejected under 35 USC 112, second paragraph for being indefinite, for reasons set forth in Paper No: 7. Applicant's arguments and amendment filed on 1/13/03 in reference to claim 24 have been fully considered but they are not persuasive. Claim 24 fails to indicate that the polypeptide is encoded by the claimed nucleic acid. Claim 24 as written reads on any protein made by the cell.

Claim Rejections - 35 USC § 101, maintained

8. Claims 4, 8, 9 and 24-29 stand rejected under 35 USC 101 for lack of utility, for reasons set forth in Paper No: 7. Applicant's arguments filed on 1/13/03 in reference to claims 4, 8, 9 and 24-29 have been fully considered but they are not persuasive.

Applicant has traversed this rejection on the premise that the disclosure of the probable fact that a protein of the instant invention functions as a monocarboxylate transporter (MCT) protein is sufficient utility. Applicant also as identified putative glycosylation site, phosphorylation site and the N-myristoylation site. In addition, Applicant asserts that the present invention, which is drawn to isolated nucleic acid molecules (SEQ ID No: 1 and 3) that encode a novel transporter protein (SEQ ID No: 2), has valuable utility within the commercial marketplace in the drug development cycle process by providing previously unidentified members of an important pharmaceutical target class. Applicant's arguments have been fully considered but are not deemed persuasive.

A nucleic acid can be patented even if it encodes no protein, provided the nucleic acid has substantial disclosed utility. When such a nucleic acid can be used as a marker for a disease or disorder or as a promoter to obtain the production of a recombinant protein in a host cell, that nucleic acid has substantial and specific utility. A protein of unknown function would also have utility if it can be employed as an indicator of a diseased state of the presence of a disorder. The only disclosed function for the protein of the instant invention, however, is as a transporter protein. It is certain that this protein

can be employed to identify compounds which can act as agonist or antagonist of that protein, but this information is without real value because the instant specification does not identify a physiological process such as blood pressure, heart rate, taste or sensation of pain which one could expect to influence by the administration of a compound that has been identified by employing a protein of the instant invention. If a protein of the instant invention was a transporter for a known compound then the protein would have utility in the purification of that compound, but the instant specification does not identify any specific compound or ion that is known to be transported by this protein. Applicant is not being required to identify a ligand for that transporter protein, **and** a physiological process mediated thereby **and** a disease or disorder for which that protein is a marker. Applicant is only required to identify **one** specific, substantial, credible utility and, as stated in the previous Office Action, the employment of this protein only as the subject of further research does not satisfy the utility requirement of 35 USC 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific benefit exists in currently available form" (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)).

Applicant asserts that the nucleic acids of the instant invention have uses within the commercial marketplace in the drug development cycle, since they encode previously unidentified members of important pharmaceutical targets. To date, each clinical agent that has been developed by measuring its interaction with a specific transporter or transmitter was evaluated against a transporter or transmitter whose native ion or substrate or ligand and physiological function were known, such as the

GABA receptors and the NMDA receptors. There are also numerous transporter proteins that do not mediate clinically significant process. More importantly, artisans knew, before they employed a specific transporter/transmitter protein to identify clinically useful compounds, which physiological process or processes they wished to manipulate and that the protein employed in their assay had an effect in that process. Even if one identifies an agonist or an antagonist for a transporter of the instant invention, this information is useless since one has no idea of what clinical effect the administration of that agonist or antagonist to an individual would have. Applicant has not shown that the claimed transporter is useful for screening drug compounds.

Applicant has also traversed this rejection on the premise that a protein encoded by the claimed polynucleotide can be employed as a tissue marker and the employment of that protein as a tissue marker is a credible, specific and substantial utility. This is probably because the PCR-based tissue screening panels indicate that this is expressed in the spleen and breast. The employment of a protein of the instant invention, or a nucleic acid encoding that protein, as a tissue specific marker is not a substantial or specific utility. All human proteins can invariably be classified into two categories, those that are expressed in a tissue or developmentally specific manner and those that are expressed ubiquitously. It can be alleged that any protein that is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein that is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such utilities are

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analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

One could just as readily argue that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. One could further extrapolate upon this premise by asserting that any item having a fixed measurable parameter can be employed to calibrate any machine or process, which measures that parameter. For example, any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store. The calibration of produce scales is certainly an important function since most states require produce scales to be calibrated and certified. Therefore, to accept Applicant's arguments that any nucleic acid encoding any protein of human origin is useful as a marker would be comparable to conceding that any object of fixed mass has *prima facie* utility as a weight standard, irrespective of any other properties possessed by that object. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that

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decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well-known process of combustion for purposes of lighting and/or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that the protein encoded thereby can be employed as a tissue marker is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a fuel source.

Claim Rejections - 35 USC § 112, first paragraph, maintained.

9. Claims 4, 8, 9 and 24-29 stand rejected under 35 USC 112, first paragraph is maintained for reasons set forth in Paper No: 7 and paragraph 8 above. Applicant's

arguments filed on 1/13/03 in reference to claims 4, 8, 9 and 24-29 have been fully considered but they are not persuasive.

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
April 4, 2003

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

**LORRAINE SPECTOR
PRIMARY EXAMINER**